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# Application for registration of a Animal Research Ethics Committee (AREC)

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- Office Use Only -

Date Received

AREC name

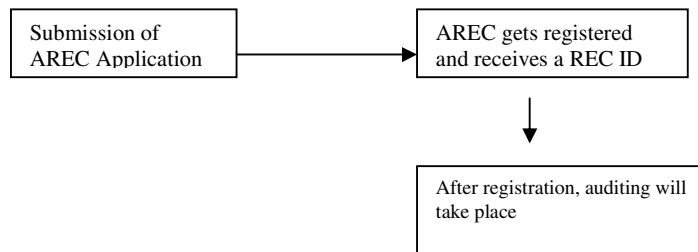
AREC ID

Name of primary organisation

Organisation ID

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## Process for of AREC Registration



# Important Information

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## Applying for registration

An organisation or independent AREC may apply for registration of a an Animal Health Research Ethics Committee (AREC) with the National Health Research Ethics Council. To be eligible for registration the organisation and AREC must demonstrate compliance with Section 73 of the National Health Act, Act No 61 of 2003.

This application must be signed by the head of the organisation or independent AREC (e.g. CEO or Vice-Chancellor, Chairperson of AREC). If the AREC serves more than one organisation, the head of each of these organisations must also sign the form.

The applicant will be advised of the outcome. To prevent unnecessary delays in the process, please ensure that the information provided is complete and accurate. You may be contacted if additional information is needed.

## Instructions

- Please type or print clearly
- All questions **MUST** be answered
- If an answer space provided is not sufficient, please attach additional pages.
- Please retain a photocopy of your completed application.

Information provided in this application must be, to the best of your knowledge, true and accurate.

**Please forward the signed, original completed form to:**

**National Health Research Ethics Council  
C/O Directorate: Health Research  
Secretariat for NHREC  
Private Bag X 828  
PRETORIA  
0001**

**Tel: 012 395-8119/012 395 8125**

**Fax: 012 395 9249**

**e-mail: [nhrec@health.gov.za](mailto:nhrec@health.gov.za)**

## Use of Information

Information relating to the AREC and the organisation will be used to determine whether the AREC meets the requirements for registration and to promote best practice with regard to ethical conduct of health related research and teaching involving animals.

Information collected during registration will be used for the following purposes:

- Send information relevant to research and ethics to the organisation and AREC;
- Monitor and review AREC compliance with the National Health Act, Act No 61 of 2003
- Generate lists of AREC/organisation contact details (excluding personal information)

- Maintain a record of correspondence, enquiries and complaints;
- Assists in the development of initiatives to support ARECs and research organisations;
- Consult with ARECs/organisations on policy with regard to the ethical use of animals in health related research and teaching.

**Privacy disclosure of information**

Information collected by the NHAREC about the ARECs and organisations is subjects to the government policy on confidentiality of information.

**Additional information on the NHREC can be retrieved from**

<http://www.doh.gov.za/nhrec/>

<http://www.nhrec.gov.za>

# Section 1

## Organisation and Animal Research Ethics Committee (AREC) Details

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### AREC details

#### 1. Name of the Organisation

#### 2. Name of AREC

#### 3. AREC Mailing Address (both physical and postal)

All AREC related correspondence would be sent to this address
Please provide address exactly as it should appear on mailing label
E-mail to be used for AREC contact/correspondence
Specific Website for AREC information (if applicable)

#### 4. AREC Contact Officer

Name	_____	
Title	Name	Surname
Position	_____	
Phone (    )	_____	
Fax (    )	_____	
E-mail	_____	

## 5. AREC Chairperson

Name	_____
	Title                      Name                      Surname
Phone	(      ) _____
Fax	(      ) _____
E-mail	_____

All correspondence to the chairperson will be sent to the “AREC Mailing Address” above.

### Organisation with primary responsibility for the AREC (‘Applicant’)

Every organisations/institutions, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council (Section 73 of the National Health Act, Act No 61 of 2003).

A health research ethics committee must:

- (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment or individual will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
- (b) grant approval for research by the relevant institution, agency, establishment or individual in instances where research proposals and protocol meet the ethical standard as described in the Regulations and guidelines governing the conduct of health research.

### Organisations with primary responsibility for the AREC (‘Applicant’)

#### 6. Name of organisation

#### 7. Name of head of organisation

#### 8. Position of head of organisation

**9. Contact details for head of organisation**

Phone (      )	Fax (      )
E-mail _____	

**10. Mailing address for head of organisation (Physical & Postal)**

All correspondence to the head of the organisation will be sent to this address. Please provide address exactly as it should appear on a mailing label

<b>Physical Address:</b>
<b>Postal Address:</b>

**11. Please indicate which category best describes the organisation (Tick one only)**

	Hospital/health service –public
	Hospital/health service – private
	University/educational institution – public
	University/educational institution – private
	Government Department
	Government statutory agency (e.g. HSRC, MRC, NRF, CSIR)
	Private Research Ethics Committee (not for profit)
	Private Research Ethics Committee (for profit)
	Other organisation/institution –not for profit
	Other organisation/institution – for profit

**12. How many organisations (stakeholders) does this AREC serve?**

**Anticipated activity level of the AREC**

**13. How many research proposals/protocols did the AREC review in the last 12 months?**

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**14. How many meetings (for the purpose of review research proposals/protocols) did and does the AREC hold respectively?**

In the past 12 months?	
In the next 12 months?	

# Section 2

## Registration Information

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Questions in this section relate to the requirements of AREC

### Establishment of AREC

Is the AREC established in accordance with:

- SANS 10386: 2008. South African National Standard : Care and Use of Animals for Scientific Purposes
- MRC Guideline 2004 : Use of Animals in Research and Training?

( Please specify which standard your REC currently adheres to. NHREC advises all ARECs to familiarize themselves with and adopt the 2008 South African National Standard.)

The organisation (s) or institution(s) must, when establishing a AREC, set out terms of reference including the scope of its responsibilities, relationship to non-affiliated researchers, accountability, mechanisms of reporting, and remuneration, if any, for members.

1. Has the AREC been established with specific terms of reference?

Yes (go to question 2)

No

1a. if NO, please provide an explanation:

2. What percentage of work best describes the role of your research ethics committee?

**Research** i.e. Review and monitoring of research proposals and associated activities

**Non-research** e.g. policy development, monitoring of animal care and use facility, training etc.

### AREC Composition

(The research ethics committee should consist of members who, collectively, have the qualifications and experience to review and evaluate the science, health aspects and ethics of the proposed research. Research ethics committees should be independent, multi-disciplinary, multi-sectoral and pluralistic.

3. Is the AREC membership constituted in accordance with the above selected guideline :

Yes (go to question 4)

No

3a. In NO, please provide an explanation



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**4. Please indicate how the membership of your AREC is constituted**

Please ensure that each individual member is assigned to one category of membership only.

Name of a member	Designated Role	Institutional Affiliation ( Yes or NO)	Qualifications	Training in the ethical use of animals in research.

**5. Please describe the role/expertise of “other/additional” members:**

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**6. What is the gender composition of the AREC?**

Number of Males	Number of Females

**7. Indemnification of AREC Members**

Members must ARECeive a formal notification of appointment and assurance that the organisation/institution will provide legal protection in respect of liabilities that may arise in the course of *bona fide* conduct of their duties as committee members.

**7a. How are AREC members informed about their appointment? (please tick)**

	Letter (posted/faxed)
	E-mail
	Personal communication (telephone)
	Other, please state:

**7b. How are AREC members selected?**

**7c. How are they notified?**

**8. Has the organisation provided assurance of legal protection for AREC members?**

Yes (go to question 9)

No

**8a. If NO, please provide an explanation of current arrangements:**

## AREC Procedures

Institutions and organisations and their ARECs must have working procedures

9. **Has the organisation and the AREC established working procedures for the following**  
*(If Yes, please indicate if these are documented or not documented. If procedures are not documented, please provide a general explanation)*

	Yes	Documented	Not Documented	No
Frequency of meetings If NO, Please explain: ..... ..... .....				
Preparations of agendas and minutes If NO, Please explain: ..... ..... .....				
Distribution of papers prior to meetings If NO, Please explain: ..... ..... .....				
Consideration and Review of research protocols If NO, Please explain: ..... ..... .....				
Methods of decision –making If NO, Please explain: ..... ..... .....				
Prompt notification of decisions If NO, Please explain: ..... ..... .....				
Reporting of unanticipated problems If NO, Please explain: ..... ..... .....				
Monitoring of research and routine and regular oversight of animal care and use facilities. If NO, Please explain: ..... ..... .....				

Reporting of monitoring activities, including problems encountered to the AREC and the institution.				
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**10(a) Has the organisation and the AREC developed procedures and processes to address conflicts of interest for AREC members? (Please tick the documented box if these are documented, if not, provide a general explanation in a space provided below)**

Yes       No       documented

**10(b) Has the organisation and the AREC developed procedures and processes to address conflicts of interest for researchers? (Please tick the documented box if these are documented, if not, provide a general explanation in a space provided below)**

Yes       No       documented

**11(a) If No in 10(a), please provide an explanation of current arrangements:**

**11(b) If No in 10(b), please provide an explanation of current arrangements:**

An AREC shall maintain a record of all research protocols received and reviewed as discussed in the above guidelines.

**12. Has the organisation developed procedures and processes to maintain records in accordance with the adopted guidelines (Please tick the documented box if these are documented, if not, provide a general explanation in a space provided below)**

**Yes**

**No**

**documented**

**14. Please attach the following AREC supporting documentation:**

- Standard Operating Procedures of the AREC**
- Application forms for ethical review**
- Confidentiality agreement form**
- Conflict of Interest Declaration**
- Checklist for submissions**

**13. If there is other information relevant to this application that may assist, please provide it below.**

# Section 3

## Declaration

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This declaration **MUST** be completed and signed by the Head of Organisation/CEO as referred in Section 1

**NOTE:** If more than one organisation/institution is responsible for this AREC, you **MUST** ensure that the authorised person of each organisation/institution signs a separate Declaration. If this is the case, you will need to photocopy this page and attach all declarations to this application.

### **I declare and undertake for the organisation**

- That I am duly authorised to sign this declaration;**
- That information supplied on this form and any attachment is true and correct;**

**Name of AREC:**

**Name of organisation:**

**Signature:** \_\_\_\_\_ **Date** \_\_\_\_\_